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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Schwarz ET AL.:

Group Art Unit: 1615

Serial No.: 09/529,543

Examiner: Tran, Susan T

Filed: May 14, 2000

DECLARATION UNDER 37 C.F.R. § 1.312

Honorable Commissioner of  
Patents and Trademarks  
Washington, D.C. 20231

SIR:

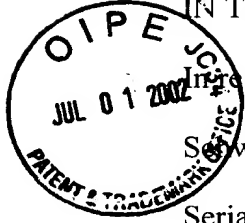
Christel Wijers, being duly warned, deposes and says:

I am a citizen of the Netherlands residing at Bensheim, Germany;  
I am a Food/Chemical Technologist by training and experience;  
the degree of Dr. ir. was bestowed on me by the University of Twente, the Netherlands in  
1996. I worked on the removal of heavy metals out of industrial wastewater by stabilized  
supported liquid membranes;  
from 1996 to 1998 I worked as Postdoc for the University Laval, Quebec, Canada;  
from 1998 to 2000 I worked for Palatinit of America, New Jersey, USA;  
since 2000 I am technical manager of LSP-BPC-Formulation, Merck KGaA, Darmstadt,  
Germany;  
I am author or co-author of numerous papers in the field of food or membrane technology;

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I have supervised the patent P9745265; Preparation of a directly moldable tableting auxiliary.

The reference US 5,536,526 (Virtanen et al.) describes the preparation of a free flowing compressible granulate which contains from 94% to 98% by weight of xylitol, another physiologically acceptable polyol such as mannitol, lactitol, maltitol or isomalt and less than 1% by weight of water. Example 2 of the Virtanen reference discloses introducing xylitol powder and a sorbitol syrup solution into a granulator.

The examiner of reference P9745265 (Schwarz et al.) conducted trials to show differences between the Virtanen spraying technique and their own co-spraying technique. The powders of TG27/01 and TG28/01 were prepared by spraying a sorbitol solution onto a xylitol bed, as described by the Virtanen reference. The powder of TG31/01 was prepared by co-spraying a xylitol-sorbitol solution onto a xylitol-sorbitol bed. The end composition of both powders was 97 wt% xylitol and 3 wt% sorbitol. The used fluidized-bed apparatus was a Glatt-WSG5, which is similar to the Shugi granulator of the Virtanen reference.

Different results were obtained as illustrated by the scanning electron microscopy (SEM) pictures. The pictures of the powders TG27/1 and TG28/1 show particle surfaces with a needle structure. This structure is very typical for sorbitol, as is known by the experts in this field. The pictures of the powder TG31/1 do not show this needle structure. The surface of the particles of powder TG31/1 is composed of a mixture of sorbitol and xylitol.

Based on these SEM pictures, it can be stated that the two different spraying techniques result in different structural properties of the xylitol-sorbitol granulates.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: May 14<sup>th</sup>, 2002

C. Wijers  
Dr. Christel Wijers

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